

# Radiologic Analysis of Balloon Sinuplasty in a Human Cadaver Model: Observed Effects on Sinonasal Anatomy

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## Abstract

**Background:** Balloon sinuplasty is increasingly used in the outpatient clinic for treatment of chronic rhinosinusitis, but radiologic analysis of its effects on sinonasal anatomy is largely uncharacterized in the known literature.

**Objective:** The purpose of this study is to examine the anatomic effects of balloon sinuplasty in a cadaveric model.

**Methods:** Five fresh cadaver heads underwent sequential endoscopic balloon dilation of maxillary ostia, frontal recess outflow tracts, and sphenoid ostia bilaterally by fellowship-trained rhinologists. Pre- and post-procedural CT imaging was obtained. CT scans were imported into Mimics™ software and sinonasal anatomy was analyzed systematically.

**Results:** Visual confirmation of balloon dilation was achieved in all 3 sites bilaterally in each cadaver. Radiologic analysis demonstrated that the frontal sinus outflow tract was appropriately dilated 60% (6/10 sites) of the time while the agger was inadvertently dilated 30% of the time (3/10). The sphenoid os was successfully dilated 70% (7/10 sites) of the time. In two cases, a posterior sphenoethmoid (Onodi) cell was dilated instead of the sphenoid. Successful dilation of maxillary os was noted 60% of the time (6/10 sites). No significant change in maxillary os was noted after balloon dilation. Normal middle turbinates were significantly medialized following balloon dilation 75% (6/8 sites) of the time.

**Conclusions:** While the goal of balloon sinuplasty is to improve natural sinonasal drainage by dilating existing outflow tracts, as evidenced by radiologic evaluation the procedure appears not to achieve this in all cases, while occasionally creating unintended changes in sinonasal anatomy as well. These unrecognized changes in anatomy may be responsible for the post-procedure change in symptomatology that some patients experience.

## Keywords

balloon sinuplasty, balloon sinus dilation, sinonasal anatomy, maxillary os, chronic rhinosinusitis

## Introduction

Chronic rhinosinusitis (CRS) is a common disease among the United States population affecting approximately 12% of people, and the burden of disease is considerable as it impacts both quality of life and has economic consequences such as missed work or school days.<sup>1,2</sup> Treatment for CRS is challenging, involving medical therapy as the primary treatment method, with

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surgical treatment offered to those patients who fail medical therapy.<sup>3</sup>

Balloon sinus dilation (BSD) is a relatively new technology used to treat CRS and recurrent acute rhinosinusitis (RARS). It was approved by the FDA in 2005<sup>4</sup> and subsequently introduced to the otolaryngology community where it has gained widespread adoption. Since its initial presentation, the use of balloon sinuplasty has increased significantly, with a greater than 500% increase in use from 2011 to 2015 compared to a modest 5.9% increase in the use of functional endoscopic sinus surgery (FESS) techniques during this same time frame.<sup>5</sup> The increase in use of BSD techniques was observed across all sinus dilation sites: sphenoid (7.0x), maxillary (5.1x), and frontal sinus (4.7x).<sup>5</sup> BSD is believed to cause its effect by dilation of the “transition spaces” of the maxillary, frontal, and sphenoid paranasal sinuses via nonconforming balloon expansion, displacing bone and soft tissue without disrupting native mucosa.<sup>4,6</sup> The goal of the procedure is a widening of sinus outflow tracts and relief of any existing obstruction.<sup>4,6</sup>

Multiple studies have shown clinical benefit of BSD,<sup>7–11</sup> and have proposed that the intervention has durable benefit greater than medical therapy<sup>12</sup> and comparable to FESS.<sup>13,14</sup> However, few studies have analyzed the anatomical results of balloon dilation in detail.<sup>7</sup> Furthermore, the intense debate about the use of BSD in otolaryngology practice<sup>5,15,16</sup> compels us to fully understand its effects on sinonasal anatomy and the extent to which it achieves its intended goal. While pre-operative CT scan is now recommended prior to balloon dilation,<sup>15</sup> post-operative scans are not recommended as a part of the American Academy of Otolaryngology – Head & Neck Surgery Clinical Consensus Statement on balloon dilation. Thus a formal radiologic examination of the effects of balloon dilation is lacking in our current literature. The purpose of our study is to examine the

anatomical effects of balloon sinuplasty in a cadaveric model via radiologic analysis.

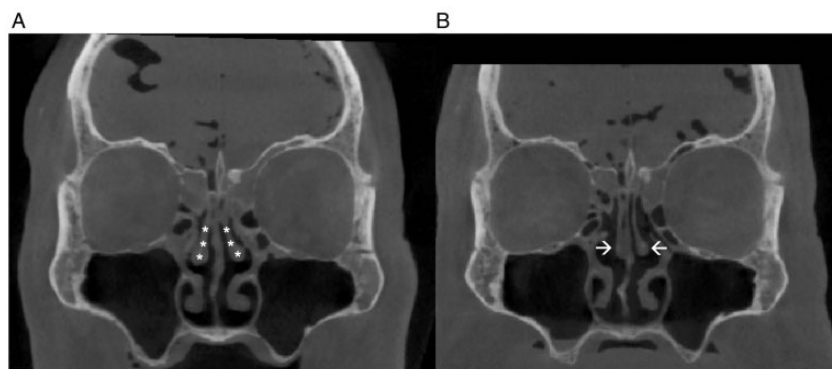
## Methods

### Materials

Five fresh cadaver heads were obtained from an organ donation facility. The specimens were assigned identification numbers. Standard endoscopy setups were used with zero degree and 45 degree 4 mm rigid nasal endoscopes (Figure 1(A)). The sinus balloon dilation system (Acclarent, Inc., Irvine, CA) contained the dilation hand pump device in addition to maxillary, frontal, and sphenoid sinus dilation tips (Figure 1(B)). The balloons were dilated via a hand pump using water according to manufacturer’s recommendations.

### Procedure

Each cadaver head underwent high resolution pre-op CT. Immediately following initial pre-operative scan, bilateral endoscopic balloon sinuplasty was performed on each cadaver head. For each dilation, a catheter wire was first threaded into the appropriate dilation site under endoscopic visualization. Light confirmation of placement of catheter into the sinus was attempted, but unreliable given the fluid in some cadaver sinuses and thus was not used. Following wire placement, the balloon catheter was advanced over the wire into the sinus ostium, and the balloon was inflated to 12 atmospheres (atm) for 30 seconds. The balloon was then deflated and removed from the sinus cavity, and the site inspected for appropriate dilation from an endoscopic view. The next sinus dilation tip was loaded onto the balloon device, and the process was repeated. The sinuses were dilated in the same sequence each time: right sided maxillary, frontal, then sphenoid sinus balloon dilations followed by an identical sequence on the



**Figure 1.** Coronal CT scan of Cadaver 1 before (A) and after (B) balloon dilation. Middle turbinates (white stars) are medialized (white arrows) following balloon dilation. Air was noted in brain tissue of cadaveric specimens before and after balloon dilation in all five cadaveric specimens. Paranasal sinus fluid also decreased post-balloon due to suctioning of fluid during procedure.

left side. All dilations were performed by the same individual surgeon, who is an attending otolaryngologist with fellowship-level training in rhinology and skull base surgery. Following balloon dilation, the cadaver specimens were each re-scanned with the same high resolution CT scanner.

### CT Scan Analysis

Side-by-side comparison of axial, sagittal, and coronal CT scans before and after balloon dilation was conducted using the image analysis software package Mimics™ (v. 18.1, Materialize, Inc., Plymouth, MI, USA). Two board certified otolaryngologists with fellowships in Rhinology/Skull Base surgery conducted the analysis. The opening of the natural ostium was measured before and after balloon sinuplasty, and successful dilation was determined to be an increase in sinus ostium diameter greater than or equal to 1 mm. While this is less than the width of a balloon, we feel there is some recoil of the surrounding tissue in the cadaveric model and our primary goal was to determine if the ostium was dilated or an inadvertent location. Discordance between the attending rhinologists in their analysis of imaging was resolved with a joint review of the imaging in question, which resulted in a mutually agreed upon interpretation.

### Results

A summary of the findings from side by side comparison of scans before and after balloon dilation is listed in

Table 1. Each individual balloon site was compared before and after balloon dilation (6 sites per cadaver), and any changes (if observed) were noted. Changes to surrounding structures adjacent to balloon sites were also compared.

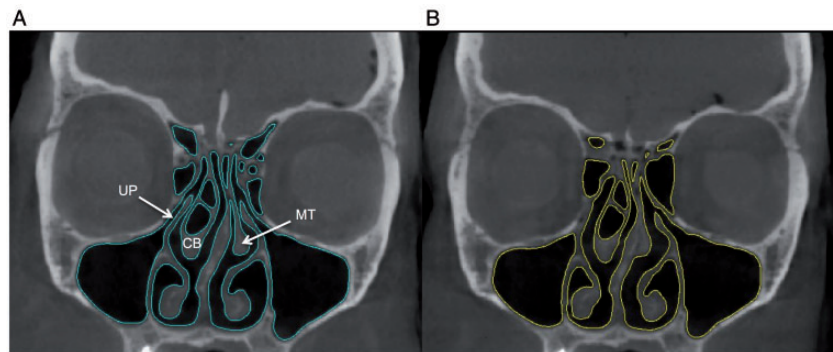
Pre-procedural fluid in the sinonasal airspaces was most notable in cadaver specimens 1 and 2, and pneumocephalus was noted in all cadaveric specimens pre- and post-balloon. A sphenothmoid (Onodi) cell was present in 2/5 cadavers, and in each instance, the Onodi cell was dilated rather than the appropriate sphenoid os. We noted obvious medialization of the middle turbinates in all but one cadaver following BSD (Figures 1 and 2). Two of the cadavers were found to have unilateral concha bullosa. The concha bullosa was not medialized in either specimen following balloon dilation (Figure 2). We also noted lateralization of the uncinate process in two cadavers following BSD, one in the presence of ipsilateral concha bullosa (Figure 2) and one without. The lateralized uncinate process appeared to be obstructing the natural maxillary os outflow tract on post-procedural imaging.

Comparing pre- and post-procedural scans, the most frequent successful dilation of natural ostia occurred in the sphenoid os (7/10 sites; Figure 3(E) and (F)), followed by frontal and maxillary ostia (6/10 sites). In the remainder of the maxillary os sites, we observed dilation of posterior fontanelle in 3/10 sites, and dilation through an iatrogenic os in one site. Compared to dilation at the frontal and sphenoid sites, we noted minimal change in os diameter with dilation of the maxillary os. In the

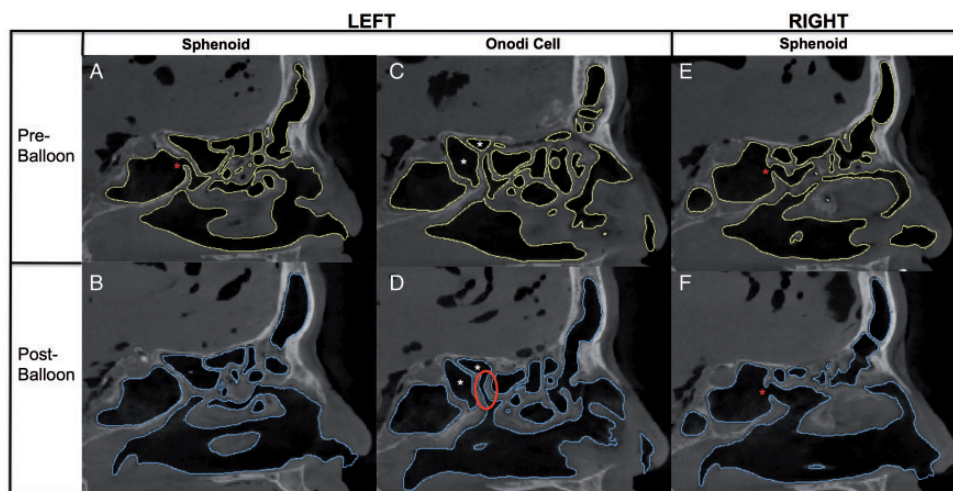
**Table 1.** Summary of Radiologic Analysis of Anatomical Changes Before and After Balloon Sinuplasty.

Cadaver	Notable Findings	Post-Balloon CT Scan Findings			
		Maxillary Dilation Site	Frontal Dilation Site	Sphenoid Dilation Site	Other Notes
1	L sided haller cells Substantial fluid in sinonasal airspace pre-op	L: iatrogenic os R: posterior fontanelle	L: dilated into agger and stopped R: successful dilation	L: successful dilation R: successful dilation	Middle turbinate medialized bilaterally
2	Onodi cell Substantial fluid in sinonasal airspace pre-op	L: successful dilation R: posterior fontanelle	L: dilated into agger and stopped R: successful dilation	L: successful dilation R: onodi cell dilated	Middle turbinates medialized bilaterally
3	L concha bullosa	L: successful dilation R: successful dilation	L: successful dilation R: successful dilation	L: onodi cell dilated R: successful dilation	L: concha unchanged R: middle turbinate medialized, R uncinate slightly lateralized
4	R concha bullosa Very hypoplastic R sphenoid sinus	L: successful dilation R: successful dilation	L: successful dilation R: dilation of suprabullar frontal cell	L: successful dilation R: dilation was of posterior ethmoid cell (non-onodi)	L: middle turbinate medialized R: concha unchanged, uncinate lateralized
5	Small R concha bullosa	L: posterior fontanelle R: successful dilation	L: successful dilation R: dilated agger cell	L: successful dilation R: successful dilation	Middle turbinates appear to be in same location

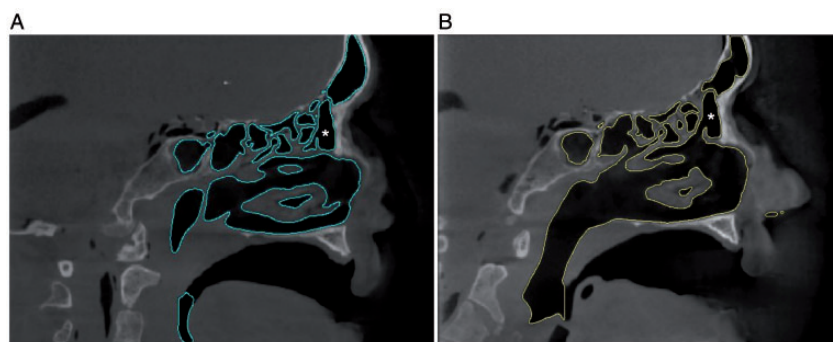
L = Left; R = Right.



**Figure 2.** Coronal CT scan of Cadaver 4 before (A, blue) and after (B, yellow) balloon dilation. Notable findings were right-sided concha bullosa (CB), lateralization of the right uncinate process (UP) and medialization of left middle turbinate (MT) following balloon dilation. The position of the concha bullosa appears unchanged, and the left maxillary os appeared to have minimal change (For interpretation of the references to colours in this figure legend, refer to the online version of this article).



**Figure 3.** Sagittal CT views of cadaver 3 before (yellow outline) and after balloon dilation (blue outline). Images capture the cross-section demonstrating the widest extent of the sphenoid os (red stars). Image B (blue, left side) demonstrates corresponding post-balloon location with loss of clear sphenoid drainage pathway due to balloon instrumentation. Instead, the Onodi cell is dilated (panel D, Onodi = white stars). Panel F shows successful dilation of the right sphenoid os compared to panel D, pre-balloon sinuplasty (For interpretation of the references to colours in this figure legend, refer to the online version of this article).



**Figure 4.** Sagittal CT scan of Cadaver 5 before (A, blue) and after (B, yellow) balloon dilation of agger nasi cell (white stars) during frontal sinus dilation (For interpretation of the references to colours in this figure legend, refer to the online version of this article).

remainder of frontal sinus sites, we observed dilation into an agger nasi cell (3/10) (Figure 4), dilation into a suprabullar frontal cell (1/10), and minimal change following dilation of the frontal in one site. In the remaining sphenoid dilation sites, we noted incorrect dilation of an Onodi cell (2/10) (Figure 3(C) and (D)), and incorrect dilation of a posterior ethmoid cell in one case. In one cadaver, dilation of the Onodi cell resulted in obstruction of the ipsilateral natural sphenoid os (Figure 3(A) and (B))

## Discussion

This study aimed to assess the anatomical changes from balloon sinuplasty, and is one of few studies exclusively dedicated to performing a radiologic analysis of these changes in a cadaver model.<sup>7</sup> While the goal of BSD is to dilate natural sinus ostia, the procedure has profound effects on paranasal anatomy that are not an intended aspect of the procedure. These unintended changes in anatomy are important to acknowledge, as they help us to understand the benefits and possible adverse effects of BSD.

In an effort to provide guidance regarding the use of BSD in clinical practice, a Clinical Consensus Statement was released by the AAO-HNS in 2018.<sup>15</sup> Of the statements included, 5 were noted to have obtained “strong consensus” with a mean Likert score of 8 or above, while the remainder qualified for “consensus” statements with a mean Likert score of 7 or above. The strong clinical consensus statements, interestingly, often specified circumstances in which use of BSD would be inappropriate. There was strong consensus that balloon dilation is not appropriate for 1) patients without both sinonasal symptoms and positive CT scan findings, 2) treatment of headache in patients who otherwise do not meet criteria for CRS or RARS, and 3) treatment of sleep apnea in patients who otherwise do not meet criteria for CRS or RARS.<sup>15</sup> There was strong consensus that a CT scan of the sinuses is a requirement before balloon dilation can be performed. Regarding outcomes, the group reached consensus that BSD can improve short-term quality-of-life outcomes in patients with limited CRS without polypsis, and BSD can be effective in frontal sinusitis.<sup>15</sup>

While the goal of BSD is dilation of natural sinus outflow tracts, our study found that in some instances, sinus instrumentation appeared to cause paradoxical obstruction of adjacent natural outflow tracts after dilation of the target site. We observed both lateralization of the uncinate process as well as dilation of agger cells and in Onodi cells when present, which impinged upon the adjacent natural outflow tracts. Interestingly, although the sphenoid sinus was the most easily appropriately dilated, we also observed that each time an Onodi cell was present, this site was accidentally dilated instead of

the target sphenoid os. As Onodi cells are present in 3.4–51% of patients,<sup>17</sup> based on these results, there appears to be a high likelihood of accidental dilation of Onodi cell. The inadvertent dilation of Onodi and agger nasi cells highlights the potential utility of a balloon system that interfaces with image guidance.

Complication rates of BSD are reportedly very low at a rate of 0.0035% per sinus of 0.01% per patient.<sup>18,19</sup> The rare complications discussed were primarily orbital penetration and CSF leak. While these findings raised concern for obstruction of adjacent outflow tracts following BSD, subsequent mucocele has not been cited as a frequent complication of the procedure. It is possible that the microfractures and shifts in tissue following balloon dilation still permit some degree of natural sinus outflow, or that such complications have not yet been captured in the follow-up data available in the literature to date.

The maxillary os proved to be a challenge to dilate at its natural opening. Prior early studies have shown similar difficulty instrumenting the natural maxillary sinus os.<sup>20</sup> The maxillary os is difficult to visualize endoscopically in its location lateral to the uncinate process, even though the design of BSD equipment aims to help the operator achieve successful dilation by including curves to facilitate os instrumentation as well as wire seeker catheter to identify the os. Additional factors, such as septal deviation or presence of a concha bullosa, may also hinder dilation. In circumstances where the natural os is difficult to visualize, accidental dilation of the posterior fontanelle is conceivable, which we observed in 3/10 dilation attempts. Unfortunately, dilation of a posterior fontanelle is not necessarily preventable using light confirmation prior to balloon dilation, as access to the maxillary sinus via the natural os and via posterior fontanelle puncture would both result in light confirmation. Dilation of posterior fontanelle has potentially harmful consequences such as recirculation syndrome.<sup>21</sup> Furthermore, the membranous nature of the medial maxillary wall surrounding the maxillary os may have confounded our results in this cadaver model. The lack of bony support around the maxillary os may prevent the soft tissue from retaining its newly dilated state, thus showing minimal change on post-balloon imaging.

Lastly, this study noted that medialization of normal middle turbinates was a fairly common side effect of BSD. These findings supported previous anatomical studies that noted lateralization of the uncinate process following BSD,<sup>7</sup> as well as medialization of middle turbinate more frequently associated with BSD compared to FESS.<sup>22</sup> Medialization of the middle turbinate is a major structural anatomical change in the nasal cavity, and we postulate that the resultant change in sinonasal airflow may contribute to symptomatic improvement patients experience following BSD via direct impact

on air flow and heat exchange in the nasal cavity.<sup>23,24</sup> This topic is the subject of current investigations by the authors.

### Limitations

This study used fresh human cadaver specimens as substitutes for live human tissue during BSD. We acknowledge that this tissue may react differently to balloon dilation compared to what we would observe in a live patient with active sinus disease. Cadaver tissue reacts differently to balloon dilation than inflamed mucosa in patient with CRS. Because of this, we did not stress actual change in the size of the post balloon ostium; but instead used a primary binary endpoint of successful dilation of the natural os. We postulate this model over estimates the rate of successful dilation in patients where pain, lack of cooperation, and mucosal inflammation would serve to hinder access to the natural ostia. As these were de-identified cadaver specimens, their sinonasal history was unknown to the operators which is not the case during in office balloon dilation. None of our cadavers had evidence of prior sinus surgery or surgically altered anatomy. Furthermore, we were unable to obtain light confirmation of sinus instrumentation. However, it is worth noting that illumination of the sinus confirms that the operator is in the correct sinus, but not necessarily that they are in the correct outflow tract and would provide no additional localization information for the sphenoid sinus. We used a guidewire style device in this study instead of a more rigid style of device for placement of the balloon. The results may not be directly applicable to other styles of devices or newer image guided balloon sinuplasty devices. However, this study does highlight and affirms other concerns regarding the precisions at which BSD is being performed.

Finally, the BSD procedures in this study were performed by two board certified otolaryngologists with fellowships in Rhinology/Skull Base Surgery. Both physicians utilize balloon sinuplasty several times per month and have been participants and instructors in numerous courses utilizing balloon sinuplasty. The rates of successful dilation in this study are similar to those reported in the literature.<sup>20</sup>

### Conclusions

Balloon sinus dilation technology has gained increasing acceptance over the past decade since its introduction to clinical practice in 2005. BSD has been shown to have positive effects on CRS patient symptomatology, and the ease of its integration in the clinic setting has made it increasingly appealing to both patients and providers. While straightforward in its goals, instrumentation of the sinuses may result in unintended changes to the

sinonasal anatomy that are worth analyzing, both for their potential deleterious effects and for understanding the physiology behind observed improvement in patient symptoms. Surgeons utilizing this procedure should take into consideration the presence of agger cells and Onodi cells when planning BSD. Further studies are warranted to investigate the changes in physiology that result from balloon dilation as well as its use amongst otolaryngologists in various clinical practice settings.

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